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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------------------|------------------------|
| 10/811,733 | 03/29/2004 | Jeffrey A. Klein | KLEIN-084B | 1689 |
| 7663 7590 05/29/2007 STETINA BRUNDA GARRED & BRUCKER 75 ENTERPRISE, SUITE 250 ALISO VIEJO, CA 92656 | | | EXAMINER BERTHEAUD, PETER JOHN | |
| | | | ART UNIT 3746 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------|--|--|
| Office Action Summary | Application No. 10/811,733 | Applicant(s) KLEIN, JEFFREY A. C | |
| | Examiner Peter J. Bertheaud | Art Unit 3746 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/28/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it exceeds the 150-word limit. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gardineer 4,674,962.

Gardineer discloses a peristaltic pump comprising a headstock 16, which comprises: a pathway (see inner wall of 16); a plurality of rollers 22 installed along the pathway, the rollers 22 being fabricated from electrically non-conductive materials (i.e. plastic, inherently non-conductive; see col. 2, lines 24-25); and a rotation mechanism 14 operative to actuate rotation of the rollers 22 along a predetermined direction. Gardineer further discloses a motor 12 to drive the rotation mechanism 14. Gardineer also discloses flexible tubing 26 extending through the pathway, wherein the flexible tubing is in contact with the rollers 22 (see col. 2, lines 42-46).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blugerman 5,447,493 in view of Goodman 5,322,070, in further view of Faeser 4,544,336, in further view of Oda 5,810,765, and still in further view of Reimels 5,580,347.

Blugerman discloses an infiltration apparatus comprising a cannula 14; a flexible tubing 13, connecting to one end of the cannula 14; a peristaltic pump 11 comprising a pathway (see wall 26) for the flexible tubing to extend through and a plurality rollers 25A-C installed along the pathway to direct flow direction of fluid flowing through the

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flexible tubing 13; a container 12, in fluid communication with the cannula 14 via the flexible tubing 13 extending through the peristaltic pump 11; and a foot pedal 16, connected to the peristaltic pump 11 via a flexible tube 13, the foot pedal 16 being operative to control operation of the peristaltic pump 11. Blugerman further discloses that the peristaltic pump further comprises a rotation mechanism 20 driving the rollers 25A-C to rotate clockwise (see Fig. 2B) or counterclockwise (see Fig. 2A). However, Blugerman does not teach the following claimed limitations taught by Goodman, Faeser, and Oda.

Goodman teaches an insufflation system comprising a foot pedal 28. Goodman further teaches that the foot pedal 28 generates and delivers at least one pulse of air to a surgical control system (see Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman, by using a foot pedal to generate and deliver at least one pulse of air to a control system in order to simplify the system and reduce costs (Goodman, col. 4, lines 60-65).

Faeser teaches a peristaltic pump comprising rollers 6, a rotation mechanism 5, and flexible tubing 1. Faeser further teaches that the plurality of rollers 6 are non-conducting (i.e. hard rubber, inherently non-conductive; see col. 4, lines 17-18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman, by using non-conductive rollers in order to reduce the weight and the noise generated by the pump.

Oda (Fig. 4) teaches an irrigation/aspiration apparatus comprising a foot pedal 17, an irrigation pump 30, and an irrigation tube 5". Oda further teaches a sensor 31 in mechanical communication with the tubing 5" and the pump 30. Oda also teaches that the sensor is capable of detecting the speed of the pump 30 as well as a flow rate of a liquid flowing through the tube 5" (see col. 5, lines 57-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman, by using the sensor to detect the speed of the pump as well as the flow rate in order to control the fluid discharge of the pump (Oda, col. 5, lines 57-67).

Blugerman in view of Oda teaches the invention as discussed above, but does not teach the following claimed limitations taught by Reimels.

Reimels teaches a system for performing surgery comprising a peristaltic pump 30, a foot pedal 14, and a handpiece 10. Reimels further teaches a sound generating device 134 in electrical communication with a sensor 114. Reimels also teaches that the sound generating device 134 is capable of generating a sound with a frequency increasing or decreasing in proportion to a speed of the pump 30 or variable with the fluid flow rate (see col. 10, lines 41-46). Reimels further teaches that the foot pedal 14 under a momentary mode is operative to switch on the peristaltic pump 30 while being depressed and switch off the peristaltic pump while being released (see col. 5, lines 58-59). Reimels also teaches that a foot pedal 20 under a continuous mode is operative to switch on and off the peristaltic pump by alternate depression (see col. 2, lines 46-48 and col. 10 lines 58-62, specifically in reference to foot pedal 20). Reimels further

teaches that the foot pedal 14 is capable of adjusting the flow rate of the fluid by controlling duration of depression applied thereto; wherein the flow rate of the fluid could be proportional to the duration of depression applied to the foot pedal 14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman in view of Oda, by having multiple modes of operation and a sound generating device in communication with a sensor in order to control the fluid discharge of the pump and to provide an indication to the surgeon of the flow rate of the fluid in the system (Reimels, col. 10, lines 41-46).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

7. Claims 12 -14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blugerman 5,447,493 in view of Oda 5,810,765, and in further view of Reimels 5,580,347.

Blugerman discloses an infiltration apparatus comprising a cannula 14; a flexible tubing 13, connecting to one end of the cannula 14; a peristaltic pump 11 comprising a pathway (see wall 26) for the flexible tubing to extend through and a plurality rollers 25A-C installed along the pathway to direct flow direction of fluid flowing through the

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flexible tubing 13; a container 12, in fluid communication with the cannula 14 via the flexible tubing 13 extending through the peristaltic pump 11; and a foot pedal 16, connected to the peristaltic pump 11 via a flexible tube 13, the foot pedal 16 being operative to control operation of the peristaltic pump 11. Blugerman further discloses that the peristaltic pump further comprises a rotation mechanism 20 driving the rollers 25A-C to rotate clockwise (see Fig. 2B) or counterclockwise (see Fig. 2A). However, Blugerman does not teach the following claimed limitations taught by Oda.

Oda (Fig. 4) teaches an irrigation/aspiration apparatus comprising a foot pedal 17, an irrigation pump 30, and an irrigation tube 5". Oda further teaches a sensor 31 in mechanical communication with the tubing 5" and the pump 30. Oda also teaches that the sensor is capable of detecting the force of pump on the tubing 5" and output an electrical signal (see col. 5, lines 57-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman, by using the sensor to detect the speed of the pump as well as the flow rate in order to control the fluid discharge of the pump (Oda, col. 5, lines 57-67).

Blugerman in view of Oda teaches the invention as discussed above, but does not teach the following claimed limitations taught by Reimels.

Reimels teaches a system for performing surgery comprising a peristaltic pump 30, a foot pedal 14, and a handpiece 10. Reimels further teaches a sound generating device 134 in electrical communication with a sensor 114. Reimels also teaches that the sound generating device 134 receives a signal from the sensor 114 and is capable of generating a sound with a frequency determined by the rate of fluid flow through the

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peristaltic pump, which would be a result of force on tubing (see col. 10, lines 41-46).

Reimels further teaches that the foot pedal 14 under a momentary mode is operative to switch on the peristaltic pump 30 while being depressed and switch off the peristaltic pump while being released (see col. 5, lines 58-59). Reimels also teaches that a foot pedal 20 under a continuous mode is operative to switch on and off the peristaltic pump by alternate depression (see col. 2, lines 46-48 and col. 10 lines 58-62, specifically in reference to foot pedal 20). Reimels further teaches that the foot pedal 14 is capable of adjusting the flow rate of the fluid by controlling duration of depression applied thereto; wherein the flow rate of the fluid could be proportional to the duration of depression applied to the foot pedal 14. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Blugerman in view of Oda, by having multiple modes of operation and a sound generating device in communication with a sensor in order to control the fluid discharge of the pump and to provide an indication to the surgeon of the flow rate of the fluid in the system (Reimels, col. 10, lines 41-46).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (*Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

8. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardineer 4,674,962 in view of Oda 5,810,765, and in further view of Reimels 5,580,347.

Gardineer discloses a peristaltic pump comprising a headstock 16, which comprises: a pathway (see inner wall of 16); a plurality of rollers 22 installed along the pathway, the rollers 22 being fabricated from electrically insulative materials (i.e. plastic, inherently insulative; see col. 2, lines 24-25); and a rotation mechanism 14 capable of driving the rollers 22 clockwise or counterclockwise. Gardineer further discloses a motor 12 to drive the rotation mechanism 14. However, Gardineer does not teach the following claimed limitations taught by Oda.

Oda (Fig. 4) teaches an irrigation/aspiration apparatus comprising a foot pedal 17, an irrigation pump 30, and an irrigation tube 5". Oda further teaches a sensor 31 in mechanical communication with the tubing 5" and the pump 30. Oda also teaches that the sensor is capable of detecting the speed of the pump 30 as well as a flow rate of a liquid flowing through the tube 5" and generate an electric signal in response to the speed or flow rate (see col. 5, lines 57-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Gardineer, by using the sensor to detect the speed of the pump as well as the flow rate in order to control the fluid discharge of the pump (Oda, col. 5, lines 57-67).

Gardineer in view of Oda teaches the invention as discussed above, but does not teach the following claimed limitations taught by Reimels.

Reimels teaches a system for performing surgery comprising a peristaltic pump 30, a foot pedal 14, and a handpiece 10. Reimels further teaches a sound generating device 134 in electrical communication with a sensor 114. Reimels also teaches that the sound generating device 134 is capable of receiving an electric signal and generating a sound with a frequency in response to the electric signal, for example a sequence of beeps in accordance to the speed of the pump 30 or variable with the fluid flow rate (see col. 10, lines 41-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Gardineer in view of Oda, by having a sound generating device in communication with a sensor in order to provide an indication to the surgeon of the flow rate of the fluid in the system (Reimels, col. 10, lines 41-46).

While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function, because apparatus claims cover what a device is, not what a device does (Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim.

9. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gardineer 4,674,962 in view of Blugerman 5,447,493.

Gardineer discloses the invention as discussed above. However, Gardineer does not teach the following claimed limitations taught by Blugerman.

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Blugerman teaches an infiltration apparatus comprising a cannula 14; a flexible tubing 13, connecting to one end of the cannula 14; a peristaltic pump 11 comprising a pathway (see wall 26) for the flexible tubing to extend through and a plurality rollers 25A-C installed along the pathway to direct flow direction of fluid flowing through the flexible tubing 13; and a foot pedal switch 16 operative to control the rotation of the rollers 25A-C. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the assembly of Gardineer, by using a foot pedal to control the rotation of the rollers in order to allow a surgeon to have his hands free when operating.

10. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardineer 4,674,962 in view of Oda 5,810,765.

Gardineer discloses the invention as discussed above. However, Gardineer does not teach the following claimed limitations taught by Oda.

Oda (Fig. 4) teaches an irrigation/aspiration apparatus comprising a foot pedal 17, an irrigation pump 30, and an irrigation tube 5". Oda further teaches a sensor 31 in mechanical communication with the tubing 5" and the pump 30. Oda also teaches that the sensor is capable of detecting a rotation condition of the rollers (see col. 5, lines 57-67). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Gardineer, by using the sensor to detect a rotation condition of the rollers in order to control the fluid discharge of the pump (Oda, col. 5, lines 57-67).

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11. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gardineer 4,674,962 in view of Reimels 5,580,347.

Gardineer discloses the invention as discussed above. However, Gardineer does not teach the following claimed limitations taught by Reimels.

Reimels teaches a system for performing surgery comprising a peristaltic pump 30, a foot pedal 14, and a handpiece 10. Reimels further teaches a sound generating device 134 in electrical communication with a sensor 114. Reimels also teaches that the sound generating device 134 is capable of generating a sound signal with a frequency increasing or decreasing in proportion to a speed of the pump 30 (see col. 10, lines 41-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the apparatus of Gardineer, by having a sound generating device in communication with a pump in order to provide an indication to the surgeon of the flow rate of the fluid in the system (Reimels, col. 10, lines 41-46).


Conclusion

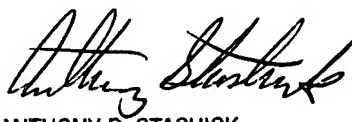
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Bertheaud whose telephone number is (571) 272-3476. The examiner can normally be reached on M-F 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Stashick can be reached on (571) 272-4561. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


PJB
5/23/07


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